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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,988	09/24/2001	Jeffrey Schlom	2026-4292US1	7849

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,988	SCHLOM ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37,89-93 and 107-131* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37, 89-93 and 107-131* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RCE

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/22/2004 has been entered. The RCE action follows:

Response to Amendment

This is a response to the amendment, paper No. 26, filed 12/18/03. Claim 89 has been amended. Claims 37, 89-93 and 107-131 are pending a considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

1. Claim 93 is still rejected under 35 U.S.C. 112, first paragraph on the same ground as stated in the previous Office Action.

2. Applicants traverse the rejection and submit that: in the world of vaccination, preventive vaccines are used against infectious disease prior to infection, whereas treatment vaccine is directed against cancer in patients where it has already occurred. Both types of vaccine, however, share the common property of being used to stimulate the immune system against the given target, such as a pathogen or a cancer cell. The claimed invention presents a new approach towards the stimulation of the immune system. The examples of the specification have shown the effectiveness of the claimed invention.

3. Applicants' argument has been fully considered; however, it is not found persuasive because no example of the specification has provided a data that supports that the use of claimed a host cell comprising the vector comprising the three co-stimulators plus an antigen is able to induce a protective immune response against any virus, bacteria and protozoan infection as well as a premalignant cell and a tumor cell development. The rejected claim 93 is not only read on a

treatment but also read on a method that is able to be used for preventive any or viral, bacterial and protozoan infection as well as cancel development. Therefore, the rejection is maintained.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

5. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

6. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 37, 107-108, 120, 122 and 123 are still rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1- 6 of U.S. Patent No. 6,548,068 on the same ground as stated in the previous Office Action.

8. Applicants argue that examiner must indicate how the claims of the instant application are sufficiently "obvious" over the other claims so as to result in an impermissible prolongation of parent term. The examiner mush show that the subject matter of claim 37, which recites, among other things, a host cell infected, transfected or induced with a recombinant vector that comprises at least one nucleic acid sequence encoding B7, ICAM-1 and LFA-3" in rendered obvious by the claims in the "068" patent. The possible of an overlapping in scope between the claims is not the test. Rather, the examiner must show that the claims in the "068" patent render obvious the claims pursued here.

9. Applicants' argument has been respectfully considered; however, it is not found persuasive because the two conflict claims are not only overlapping in the scope but also it would have been obvious for a person with ordinary skill in the art to make a host cell transfected with a recombinant vector comprising the three co-stimulatory factors that are already disclosed and told in the cited patent "068' that are already approved to be an effective co-stimulatory factors that is able to produce an enhanced immune response against the co-administrated antigen.

10. The current application is directed to a host cell infected, or induced or transfected with are recombinant vector comprises at least one nucleic acid sequence encoding B7, ICAM-1 and LFA-3 as well as a nucleic acid sequence encoding a target antigen. The claim 1 of patent "068" is directed to a host cell infected with a recombinant viral vector comprising one costimulatory molecules selected from B7.1, and B7.2, claim 4 further recites that the vector comprises one or more immunostimulatory molecule selected from ICAM-3 and LFA-3 (Claim 4). In this content, the recombinant virus is considered as a recombinant vector in the art. Because the current rejected claims do not exclusively limit the co-stimulatory factors are encoded by one nucleic acid sequence, the scope of the claimed invention also read on a recombinant vector comprises more than one DNA sequences encoding those immune stimulatory selected from sequences encoding the co-stimulatory molecules ICAM-3 and LFA-3 absence unexpected result because the host cells comprise the three co-stimulatory factors plus an antigen is already disclosed to be an effective molecules in patent "068". Therefore, the claimed invention is still maintained.

New Ground Rejection

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 89-93, 107-120 and 122-125 are still rejected under 35 U.S.C. 112, first paragraph on the same ground as stated in the previous Office Action, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention directed to a host call infected, transfected or induced by a recombinant vector that comprising sequences encoding B7, ICAM-1 and LFA-3 plus any of all antigen as listed in claims 107-120 and 122-125 except the antigen CEA.

13. Applicants traverse the rejection and submit that the written description of the genus can be shown by disclosure of structure characteristics, functional characteristics that correlate with structure or combinations thereof. Applicants further assert that the structural requirements set forth in claims 107-120 and 122-125 find correspondence in the specification at page 33-37 and original claims 19-31 because the original claims a part of the specification under the first paragraph of 35 USC 112.

14. Applicants' argument has been fully considered; however, it is not found persuasive because 35 USC 112 requires inter alia that "a patent specification contain a written description of the invention and the manner and process of making and using it in such full clear and concise terms as to enable one skilled in the art to make and use the invention". The specification of on page 33-37 and claims 19-31 have been reviewed, they are just the names of the different pathogens. There is no description that support at the application was filed that applicants have already have some of the viral vector comprising the three co-stimulatory molecules with some species of antigens. Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains some name of pathogenic antigen, which may enable a skilled artisan to produce a particular host cells because each given antigen is immungentic. But it still makes no reference to the host cells in question, the "written description" requirement has not been met even though the description may be enabling.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

16. Claims 37, 107-108, 120, 122 and 123 rejected under 35 U.S.C. 102(e) as being anticipated by Schlom et al. (US patent No. 6,548,068B1).

17. Schlom et al. teach a host cell infected with a recombinant vaccinia virus encoding an antigen of a disease and a gene or genes encoding a co-stimulatory sequence or sequences of B7-1 and/or B7.2 and ICAM-3 and LFA-3. The antigen is a tumor antigen selected from the group consisting of MART-1 MART-2, ECA, Muc-1 or Muc-2 etc. (See claims 1-4). Because the recombinant virus is also considered as a viral vector; therefore, the claimed invention is anticipated by the cited reference.

18. The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li
May 10, 2004

JAMES HOUSEL 5/7/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600